SINGLE PROJECT ASSURANCE

THIS IS A SAMPLE SINGLE PROJECT ASSURANCE (SPA) FOR AN INSTITUTION WHICH CURRENTLY DOES NOT HAVE A MULTIPLE PROJECT ASSURANCE (MPA) ON FILE (Rev. June 1998)

FULL BOARD REVIEW REQUIRED OF IRB

Using this sample, type on Institutional Letterhead supplying where indicated, information specific to the proposed research activity and your Institution, and include the required certification on the endorsement page.

[Institution Name]

Assurance of Compliance with Department of Defense Regulations for Protection of Human Research Subjects

[Institution Name] hereinafter known as the "institution," hereby gives assurance that it will comply with the Department of Defense (DOD) regulations for the Protection of Human Research Subjects (DOD Regulation 32 CFR 219, Part 1 and, where applicable, HHS Regulation 45 CFR 46, Subparts B, C and D), and Title 10, United States Code, Section 980 (hereinafter referred to as 10 USC 980) as specified below.

PART 1

Ethical Principles and Institutional Policies Governing Research Involving Human Subjects

I. Applicability

Except for research exempted or waived under the DOD regulations 32 CFR 219.101, and 10 USC 980, Part 1 of this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to federal regulation, if:

A. the research is sponsored by this institution, or
B. the research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities, or
C. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
D. the research involves the use of this institution's nonpublic information to identify or contact human research subjects or prospective subjects.

II. Ethical Principles Governing Human Subjects Research

This institution is guided by the ethical principles regarding all research involving humans as

subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") and as specified below.

A. This institution recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice as stated in the Belmont Report and will apply these principles in all research covered by this Assurance.

B. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

III. **Policies**

A. This institution acknowledges that it and its investigators bear full responsibility for the performance of all research covered by this Assurance, including full responsibility for complying with Federal, state, and local laws as they may relate to such research.

B. This institution assures that before human subjects are involved in research, proper consideration will be given to:

(1) the risks to the subjects,
(2) the anticipated benefits to the subjects and others,
(3) the importance of the knowledge that may reasonably be expected to result,
(4) the informed consent process to be employed,
(5) the provisions to protect the privacy of subjects, and
(6) the additional safeguards for vulnerable populations.

C. This institution recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

D. This institution encourages and promotes constructive communication among the institutional officials, research administrators, department heads, research investigators, clinical care staff, human subjects, and all relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

E. This institution will exercise appropriate administration overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

PART 2

IRB, Institution, and Investigator Compliance with 32 CFR 219 and 45 CFR 46 and 10 USC 980

I. Applicability

Part 2 of this Assurance applies to the following research project which is conducted or sponsored by this institution and supported by the DOD.

Project title: [Title of study]

Human Subjects Protection Division (HSPD) Log No.: [Assigned by HSPD]

Project investigator or Director: [Principal Investigator]

II. Institutional Responsibilities

A. This institution has complied and will continue to comply with the requirements of 32 CFR 219 Part 1, and 45 CFR 46 Subparts B, C, and D, and 10 USC 980, as specified below.

B. In accordance with the compositional and quorum requirements of 32 CFR 219.107 and 219.108, the Institutional Review Board (IRB) designated in Part 3 and in the attached roster is responsible for the initial and continuing review of this project.

C. This institute has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and record keeping duties.

D. In addition to the review and approval of the IRB, this institution has reviewed and sponsors the project referenced above.

III. **IRB Review**

A. The IRB shall review and have the authority to approve, require modification in, or disapprove this research or proposed changes in it before human subjects may be involved.

B. The convened IRB reviewed and approved the above project.

C. The IRB determined, in accordance with the criteria found at 32 CFR 219.111, and where applicable, 45 CFR 46 Subparts B, C, and D, and 10 USC 980, that protection for human research subjects are adequate.

D. The IRB has the authority to suspend or terminate approval of the above referenced research in accordance with 32 CFR 219.113 for (1) non-compliance with 32 CFR 219, and this Assurance document or the IRB's requirements, and (2) for elimination of unexpected serious harm to subjects.

E. The IRB has determined that legally effective informed consent **[copy of document must be attached unless specified otherwise by HSPD]** will be obtained in a manner and method which meets the requirements of 32 CFR 219.116 and 219.117.

F. Certification of IRB approval, at least annually shall be submitted to the HSPD for a non-competing continuation and/or additional involvement of human subjects.

G. Continuing reviews by the IRB shall be conducted at intervals appropriate to the degree of risk, but not less than once per year (32 CFR 219.109[e]). The IRB may be called into an interim review session by the Chairperson at the request of an IRB member or Institutional Official to consider any matter concerned with the rights and welfare of human subjects. Documentation of continuing review must be provided to the HSPD no later than one year from last review date.

H. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 32 CFR 219.115.

I. The IRB shall report promptly to institutional officials and the HSPD:

(1) any serious or continuing noncompliance by investigators with the requirements of the IRB,
(2) any suspension or termination of IRB approval,
(3) any unanticipated problems or injuries involving risks to subjects or others, and
(4) any changes in this research activity which are reviewed and approved by the IRB.

J. Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children as required under Subparts B, C, and D of 45 CFR 46 and 10 USC 980. The IRB will notify HSPD promptly when IRB membership is modified to satisfy the requirements at 45 CFR 46.304 and when the IRB fulfills its duties under 45 CFR 46.305(c).

K. The IRB will comply fully with the requirements of all applicable Federal policies and guidelines, including those concerning notification of sero-positivity, counseling, and confidentiality of subjects.

L. The IRB will comply fully with 10 USC 980 which states: if an individual cannot give his/her own consent, and there is no intent to benefit the subject, (for example, minors) he/she cannot be entered into a study funded by the DOD. <u>This is legally binding and there will be no exceptions.</u>

IV. **Research Investigator Reporting Responsibilities**

A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects for complying with all applicable provisions of this Assurance and 32 CFR 219, 45 CFR 46 and 10 USC 980.

B. Research investigators shall report promptly to the IRB proposed changes in this research activity and the changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects. Any change in the investigator or change to the protocol shall be reported to the HSPD.

C. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others. Any serious and unexpected adverse event(s) shall be reported to the HSPD.

PART 3

Certification of IRB Approval and Institutional Endorsement

Project title: [Title of study]

HSPD Log No.: [Assigned by HSPD]

Project Investigator or Director: [Principal Investigator]

Date of IRB Approval: [ ]; Date of Next IRB Review: [ ]

The officials signing below assure that the project referenced above was approved by the IRB on the date indicated and that the project will be conducted in accordance with the requirements of Title 32, Part 219 and Title 45, Part 46 of the Code of Federal Regulations, 10 USC 980, and this Assurance document. A dated roster listing the current membership of the

designated IRB is attached:

I. **Authorized Official** of the Institution Providing This Assurance

Signature_____Date:_____

Signature block
Official Institutional Title
Address
Telephone number
FAX number

II. **Authorized Official** of the Institution with the IRB
(Include only if different from the Institution above)

This institution authorizes the designation of its IRB for review of the project referenced in this Assurance.

Signature_____Date:_____
Signature block
Official Institutional Title
Address
Telephone number
FAX number

III. IRB Chairperson
(Must be completed in all cases [see IRB membership list])

Signature_____Date:_____
Signature block
Address
Telephone number
FAX number

MPA number if applicable: [ ]

IV. Responsible Project Investigator or Director at Institution Providing this Assurance

I have attached copies of all requested and approved Informed Consent Documents to be used in this project unless the designated IRB operates under a DOD-approved Multiple Project Assurance (MPA) or unless DOD has indicated otherwise.

Signature_____Date:_____
Signature block [Principal Investigator]
Address
Telephone number
FAX number

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- SPACE BELOW FOR DEPARTMENT OF DEFENSE -

All parts of this Assurance are in compliance with the requirements of Title 32, Part 219, Title 45, Part 46 of the Code of Federal Regulations, and 10 USC 980.

DOD Approving Official

Signature_____Date: _____

Name: Ms. Yvonne Higgins, Chief
Address: Human Subjects Protection Division (HSPD)
U.S. Army Medical Research and Materiel Command,
Fort Detrick, Frederick, MD 21702-5012

Telephone #: 301-619-2165\2166
FAX #: 301-619-7803

ASSURANCE NUMBER: _____*

* Effective for 5 years from date of issue, or upon completion of project, and must be renegotiated with HSPD.

INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP

NAME OF IRB AGENCY OR COMMAND_____

Address and Phone No Chairperson only _____

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_____

_____

Members' Names			Highest	Scientific	Affiliation
First	MI	Last	Degree	Specialty	w/Institution
(1)					
(2)					
(3)					
(4)					

(1) Denotes Chairperson (3) Denotes IRB alternates
(2) Denotes IRB members (4) Denotes non-voting IRB attendee
(expert or technical expertise)